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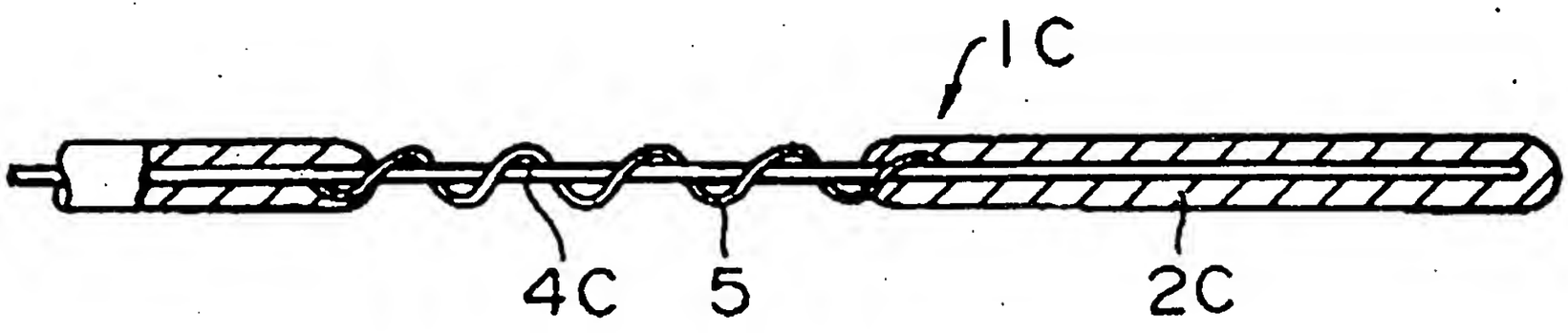
(54) WIRE FOR OPENING OBSTRUCTED PART OF BLOOD VESSEL.

(57) A wire for opening the obstructed part of a blood vessel comprising a plurality of projections or grooves formed on the forward end zone of a flexible or resilient wire body, or spiral parts provided starting at the tip of the wire body spaced apart from each other and left after a part of the material wire body corresponding to said spiral parts is cut away.

FIG. 4



EP 0 473 790 A1

TECHNICAL FIELD

The present invention relates to a wire for opening (or enlarging) a blood vessel, particularly, an obstructive or stenosed region in a coronary artery, to pass blood flow (or pass much blood flow).

BACKGROUND ART

Stenosis of coronary arteries due to arteriosclerosis or the like causes myocardial infarction within a short period of time after having been broken out if the stenosis is left alone. Accordingly, urgent or emergent medical treatment is required. As a method of medical-treating (opening) the stenosed region, there have conventionally been known a method using a balloon catheter, and a method using a thrombolytic agent or drug.

The balloon catheter is provided with a inflatable balloon at a distal end of a catheter body (refer to Japanese Utility Model Laid-Open No. SHO 61-130240 and Japanese Utility Model Laid-Open No. SHO 61-171941). The balloon catheter is inserted into a vascular stenosed region under a condition that the balloon is constricted, and fluid such as physiological saline, carbonic acid gas, a contrast medium or the like is injected into the balloon from a passage in the catheter body, to inflate the balloon. Thus, the stenosed region is enlarged, thereby opening the stenosed region.

As the thrombolytic drug, there are known Streptokinase, Urokinase or the like. The thrombolytic drug is directly administrated into the coronary artery, dissolves a thrombus within the artery, and opens the same.

However, the method using the balloon catheter only enlarges tissues of the artery, but does not remove the stenosed region. Accordingly, the balloon catheter method has a disadvantage that restenosis occurs in a relatively short period of time and with a high probability (for example, with a probability of 44% within three (3) months). Further, the method has also a disadvantage that a complication such as a myocardial infarction, cardiogenic shock or injury to the artery or the like occurs.

The method using the thrombolytic drug has a tendency of hemorrhage, gastrointestinal bleeding, intracerebral bleeding or the like as a side effect, and has also a low percentage of success such as about 50%.

In view of the above, it is an object of the invention to provide a wire for opening a stenosed region of coronary artery, which has no defects or disadvantages described above.

DISCLOSURE OF THE INVENTION

The aforesaid object is achieved by the arrangement that a plurality of projections or grooves are formed within a range of a distal end of a flexible or elastic wire body, or the arrangement that a spiral body is provided in spaced relation to a distal end of a flexible or elastic wire body, and a portion of the wire body within a range of the spiral body is resected.

In this case, the distal end of the wire body, the projections or the spiral body may be made of a high-electricity resistive material or a high magnetic material.

Further, an elastic core may be embedded in the wire body.

Furthermore, the wire body may be bent at a location between the distal end of the wire body and the projections, the grooves or the spiral body.

Moreover, the arrangement may be such that a passage is formed in the wire body, and the passage is open to a surface of the wire body within a range of the distal end of the wire body so that a drug is supplied into the passage. Further, the arrangement may also be such that a glass fiber is inserted through the passage, and a laser is supplied through the wire from the outside.

In the case of the wire for opening the stenosed region of coronary artery, according to the invention, the configuration or shape of each of the projections at a formed section is, for example, a spherical shape, a circular cylinder shape, a spiral shape, a circular truncated cone shape, or the like, and the configuration of each of the grooves is, for example, a ring-like shape, a spiral shape, a semicircular shape or the like. Further, the number of the projections and the grooves at the formed section is optional. The wire body is made of, for example, a plastic material, and the projections are made of a material identical with that of the wire body, or are made of another material such as, for example, a plastic material different from the first-mentioned plastic material, or are made of a high-electricity resistive material or a high magnetic material. The core consists of a metal wire, for example, which functions to supply high-frequency current, functions to reinforce the wire body, or functions to raise elasticity of the wire body.

In connection with the above, in the wire for opening the stenosed region of the artery, according to the invention, the term "opening the stenosed region of the artery" includes enlargement of a stricture section in a blood vessel.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a cross-sectional view of a region of a distal end of a wire for opening a stenosed region of coronary artery, according to a first embodiment of the invention;

Fig. 2 is a cross-sectional view of a region of a distal end of a wire for opening a stenosed region of coronary artery, according to a second embodiment of the invention;
Fig. 3 is a fragmentary cross-sectional view of a region of a distal end of a wire for opening a stenosed region of coronary artery, according to a third embodiment of the invention;
Fig. 4 is a cross-sectional view of a region of a distal end of a wire for opening a stenosed region of coronary artery, according to a fourth embodiment of the invention;
Fig. 5 is a cross-sectional view of a region of a distal end of a wire for opening a stenosed region of coronary artery, according to a fifth embodiment of the invention;
Fig. 6 is a cross-sectional view of a region of a distal end of a wire for opening a stenosed region of coronary artery, according to a sixth embodiment of the invention;
Fig. 7 is a cross-sectional view of a region of a distal end of a wire for opening a stenosed region of coronary artery, according to a seventh embodiment of the invention;
Fig. 8 is a cross-sectional view of a region of a distal end of a wire for opening a stenosed region of coronary artery, according to an eighth embodiment of the invention;
Fig 9 is a view showing a use of the wire for opening the stenosed region of coronary artery; and
Fig. 10 is a fragmentary enlarged view in Fig. 9, showing a state that the stenosed region is open.

BEST MODE FOR CARRYING OUT THE INVENTION

Embodiments of the invention will be described below with reference to the drawings.

Fig. 1 shows in a cross-sectional view a range of a distal end of an elongated wire 1 for opening an obstructive or stenosed region of coronary artery, according to a first embodiment of the invention. In Fig. 1, the reference numeral 2 denotes a wire body; 3, projections formed on the wire body 2; and 4, a core embedded in the wire body 2.

The wire body 2 is made of a material (flexible material) which is deformed by an external force, and is not restored to its original configuration by itself, or a material (resilient or elastic material) which, after having been deformed, is restored to its original configuration, at the time of the use of the wire 1 for opening the stenosed region of coronary artery (at the time of insertion into an artery). For example, the wire body 2 is made of a plastic material such as enamel, Teflon (trade name) or the like. Moreover, the wire body may have a coating layer such as hydrophilic polymer or the like, on the distal end portion of the wire body. Further, the wire body may have a coating layer such as tungsten-mixed polyurethane elastomer or the like, on a portion of the wire body except for the distal end portion thereof. Further, the wire body 2 is circular in transverse cross-section, and have a diameter such as 0.5 ~ 1.2 mm. The wire body 2 has a distal end which is so rounded as not to injure the coronary artery or the like.

Each of the projections 3 is formed substantially into a spherical shape. In the illustrated embodiment, three projections are provided. However, the number of the projections is optional. The outer diameter of each projection 3 is about 0.1 ~ 2.0 mm larger than the diameter of the wire body 2. The interval or spacing between the adjacent projections 3 is e.g. 0.5 ~ 5.5 mm. Each projection 3 has an entire length of 5 ~ 40 mm. The spacing between the projection 3 adjacent to the distal end of the wire body 2 and the distal end thereof is e.g. 0 ~ 50 mm, preferably, 10 ~ 20 mm.

The core is made of a material (elastic material) which is restored to its original configuration after having been subjected to an external force and been deformed. For example, it is made of stainless steel, an alloy (nickel - titanium alloy or the like), a piano wire material, an amorphous metal, gold, a plastic material, or the like. The core 5 has a function of reinforcing the wire body 2, or a function of increasing elasticity of the wire body 2. The core 5 does not reach the distal end of the wire body 2, but terminates at a location between the distal end and the projection 3. The core 5 has a diameter such as 0.1 ~ 1 mm.

Fig. 2 shows a wire 1A for opening a stenosed region of coronary artery, according to a second embodiment. The wire 1A has a plurality of projections 3A each of which is formed into a circular cylinder shape. In order to facilitate insertion of the wire into a coronary artery which is stenosed, a portion of the wire 1A between the distal end thereof and the projection 3A is bent through an angle α. In this case, a wire body 2A is made of a material (flexible material) which is deformed by an external force, and is not restored to its original configuration by itself, or a material (resilient or elastic material) which, after having been deformed, is restored to its original configuration, at the time of the use of the wire 1A for opening the stenosed region of coronary artery. A core 4A is made of a material (elastic material) which, after having been subjected to an external force, is deformed, and thereafter restored to its original configuration, at the use of the wire 1A for opening the stenosed region of coronary artery. Further, it is convenient if the core 4A is made of a material which, when an

operator or the like applies an external force larger than an elastic limit, to the material, can plastically be deformed into an appropriate angle α (the angle α is an optional angle equal to or less than 90°), or can be deformed into an appropriate configuration. The reason is as follows. That is, in order to facilitate insertion of the wire through the stenosed region of coronary artery, the operator can deform the portion of the distal end of the wire 1A for opening the stenosed region of the coronary artery, in accordance with parts of the stenosed region. The core 4A reaches a location adjacent to the distal end of the wire body 2A.

Fig. 3 illustrates a wire 1B for opening a obstructive or stenosed region of coronary artery, according to a third embodiment. The wire 1B is different from the wire 1 for opening the stenosed region of coronary artery, according to the first embodiment, only in that a projection 3B is formed by a spiral element. The projection 3B may integrally be made of a material the same as that of a wire body 2B, or may separately be made of other materials. For example, in the case where the projection 3B is made of a plastic wire or a metal wire (the projection may be made of a core 4B) having an affinity to a human body, it is necessary that both ends of the plastic wire or the metal wire are embedded in the wire body 1B so as not to be exposed. The spiral element 3B has a pitch of 0.5 ~ 5 mm.

Fig. 4 illustrates a wire 1C for opening an obstructive or stenosed region of coronary artery, according to a fourth embodiment. The wire 1C is arranged such that a spiral element 5 instead of the projections is provided in concentric relation to a core 4C, and a portion of a wire body 2C, which is within a range of the spiral element 5, is resected. The spiral element 5 is made of a metal wire (the spiral element may be the core 4B) having an affinity to a human body, a metal wire having high resistance to electricity, a metal wire having high or strong magnetism, or a plastic wire. The spiral element 5 has an outer diameter which may be larger than that of the wire body 2C, or may be smaller than the latter. A blank wire of the spiral element 5 has a diameter of 0.1 ~ 1 mm, and a pitch of 0.5 ~ 5 mm.

Fig. 5 illustrates a wire 1D for opening an obstructive or stenosed region of coronary artery, according to a fifth embodiment. The wire 1D is arranged such that a wire body 2D is made of a resilient or elastic material, and the wire 1D is provided with a plurality of ring-like grooves 6 in substitution for the projections or projection.

Fig. 6 illustrates a wire 1E for opening an obstructive or stenosed region of coronary artery, according to a sixth embodiment. The wire 1E is arranged such that each of a plurality of projections 3E is in the form of a circular truncated cone. Also in this case, a wire body 2E is made of a resilient or elastic material, similarly to the fifth embodiment shown in Fig. 5.

Fig. 7 illustrates a wire 1F for opening an obstructive or stenosed region of coronary artery, according to a seventh embodiment. In the case of the wire 1F, a plurality of projections 3F are arranged only on one side of a wire body 2F, and a passage 11 through which a drug (a vasodilation drug, a thrombolytic drug or the like) is supplied, is formed in the wire body 2F. The passage 11 opens to the wire surface within a range of the projections 3F and at a distal end of the wire. A flow direction of the drug is indicated by the arrows.

Fig. 8 illustrates a wire 1G for opening an obstructive or stenosed region of coronary artery, according to an eighth embodiment. The wire 1G is provided with a spiral element 5G, similarly to the fourth embodiment shown in Fig. 4. However, the wire 1G has an interior thereof which is not provided with a core, but is formed with a passage 11G. The passage 11G opens to a surface of a wire body 2G at a location in short of the spiral element 5G. The arrangement may be such that a glass fiber is inserted through the passage, and a laser beam is capable of being applied from the outside.

A method of opening an obstructive or stenosed region of coronary artery, by the use of the brushing wire 1 for opening the coronary revascularization, will next be described with reference to Figs. 9 and 10. The revascularization is effected in the following order:

1) First, an artery (not shown) is pierced, and a sheath (not shown) is held within the artery.

2) A heart catheter 7 is inserted into the artery, and is led to a heart 8.

3) A distal end of the catheter 7 is inserted into a coronary artery 9, a contrast medium is injected, and the coronary artery is examined by fluoroscopy, to confirm a stenosed region 10.

4) The wire 1 for coronary revascularization is inserted into the catheter 7, and is put into the coronary artery 9, and is led to the coronary-artery stenosed region 10. At this time, since a portion of the wire between the distal end of the wire and the projection 3 serves as a guide, it is possible to easily insert the wire 1 into the stenosed region.

5) The wire 1 for coronary revascularization is operated to reciprocate the projections 3 several times between a location in front of the stenosed region 10 and in rear thereof, thereby enlarging a lumen while shaving the stenosed region. At this time, the arrangement may be such that high frequency current is applied to a high resistive material through the core, and a high fre-

quency magnetic field is applied to a ferromagnetic body, to cauterize and enlarge the stenosed region.

6) Lastly, the wire 1 for coronary revascularization is retracted into the catheter 7 so that the catheter 7 is withdrawn from the artery.

As described above, the projections 3 on the wire 1 for coronary revascularization are located at the stenosed region and are reciprocated, whereby it is possible to cut and remove a thrombus, a hypertrophied vascular endothelium, cholesterol and the like existing in the stenosed region, to reopen blood stream to a heart or the like. Further, application of the high frequency current through the core, and application of a high frequency magnetic field through the core enable the above-described thrombus and the like to be cauterized and removed.

The conventional balloon catheter is confined merely to enlargement of such hypertrophied section without removing the same. Accordingly, as time elapses, there is a very high probability that the lumen is depressed to cause restenosis. However, in the case where the wire 1 for coronary revascularization, according to the invention, is used, since hypertrophied sections within the artery are removed, a probability that the restenosis occurs becomes very low. Furthermore, by the use of wires of various sizes, it is possible to reopen a stenosed region of coronary artery to enlarge an inner diameter of the coronary artery stepwise. Since the distal end of the wire is very rich in elasticity, a complication such as injury to a coronary artery, cardiogenic shock or the like is difficult to occur so that the wire exhibits effectiveness in any coronary arteries having a small diameter.

Moreover, a tendency of hemorrhage does not occur, and the percentage of success is very high, as compared with a conventional method in which a thrombolytic drug is used.

Further, since the elastic portion between the distal end of the wire and the projection 3 serves as a guide, it is possible to easily insert the wire into the stenosed region of coronary artery. Furthermore, since slippage of the surface of the wire body 2 is superior, there is no case where the inner wall of the coronary artery is injured. Moreover, as described above, since it is sufficient only that the wire 1 is inserted into the coronary artery and is reciprocated, operating manipulation or handling is simple and easy. Further, since the structure or construction of the wire 1 is simple, a manufacturing cost therefor is low.

The embodiments of the invention have been described above. However, the invention is not limited to the aforesaid embodiments. For example, in the case of the wire 1, 1B or 1C for coronary revascularization, according to the first, third or fourth embodiment, it is not necessarily required to provide the core, like the wire 1D, 1E, 1F or 1G for coronary revascularization, according to the fifth, sixth, seventh or eighth embodiment. In the case where the core is provided, the core may reach the distal end of the wire body, or may reach a location slightly in short of the distal end of the wire body. Furthermore, also in the case of the wire 1, 1A, 1B, 1C and 1D for coronary revascularization, according to each of the first ~ sixth embodiments in which the passage 11 or 11G is not provided, it is possible to provide a passage. In this case, the arrangement may be such that the core and the passage are provided in the wire body in parallel relation to each other, and the passage larger than the core is formed so that the core is arranged within the passage. Moreover, the opening location of each of the passages 11 and 11G may be anywhere within the range of the distal end of the wire, and the number of the openings (outlets) is optional. Further, it is possible to form the projections 3, 3A, 3B, 3E and 3F and the grooves 6 into any various configurations or shapes, and both the projections and the grooves may be provided. Furthermore, the number or the projections and the grooves is optional, and the arranging locations thereof may be anywhere if the arranging locations are within the range of the distal end of the wire (they may be at the distal end or may be in the vicinity of the distal end).

As described above, the wire for coronary revascularization, according to the invention, has a very low probability that restenosis after operation occurs, and a complication such as a myocardial infarction, cardiogenic shock, coronary-artery injury or the like is difficult to occur. Moreover, a tendency of hemorrhage is low, and the percentage of success is very high. Further, there are produced advantages that the manufacturing cost is low, and operating manipulation or handling is simple and easy.

Claims

1. A wire for coronary revascularization, said wire being adapted to be inserted into a catheter, characterized in that a plurality of projections or grooves are formed within a range of a distal end of a flexible or elastic wire body.

2. A wire for coronary revascularization, according to claim 1, characterized in that each of said projections is made of a material selected from the group consisting of a plastic material, a high-electricity resistive material and a high magnetic material.

3. A wire for coronary revascularization, said wire

being adapted to be inserted into a catheter, characterized in that a spiral element is provided in spaced relation to a distal end of a flexible or elastic wire body, and that a portion of the wire body within a range of the spiral element is resected.

4. A wire for coronary revascularization, according to claim 3, characterized in that said spiral element is made of a material selected from the group consisting of a high-electricity resistive material and a high magnetic material.

5. A wire for coronary revascularization, according to any one of claims 1 ~ 4, characterized in that an elastic core is embedded into the wire body.

6. A wire for coronary revascularization, according to any one of claims 1 ~ 5, characterized in that the wire body is bent at a location between the distal end of the wire body and the projections, the grooves or the spiral element.

7. A wire for coronary revascularization, according to any one of claims 1 ~ 6, characterized in that a passage is formed in the wire body, and that the passage is open to a surface of the wire body within a range of the distal end of the wire body.

8. A wire for coronary revascularization, according to claim 7, characterized in that said passage is a passage for supplying a drug.

9. A wire for coronary revascularization, according to claim 7, characterized in that said passage is a passage through which a glass fiber is inserted, and that a laser is applicable through the glass fiber.

10. A wire for coronary revascularization, said wire being adapted to be inserted into a catheter, characterized in that a core is provided within a flexible or elastic wire body, that a spiral element made of a high-electricity resistive material is arranged in spaced relation to a distal end of the wire body and in connected relation to said core, and that high frequency current is applied to the spiral element so as to be capable of heating.

11. A wire for coronary revascularization, said wire being adapted to be inserted into a catheter, characterized in that a distal end of a flexible or elastic wire body is made of a high magnetic material, and that the distal end of the wire body is capable of heating by a high-frequency magnetic field.

FIG. 1

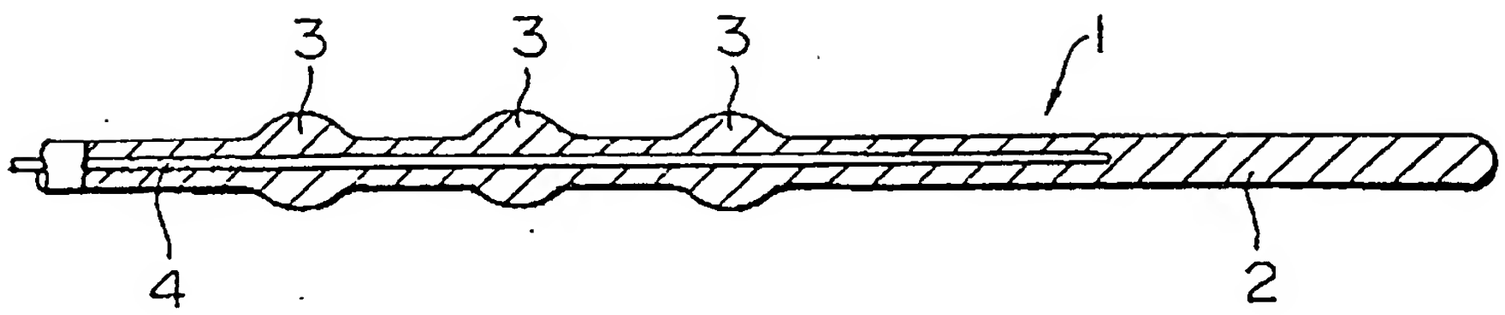


FIG. 2

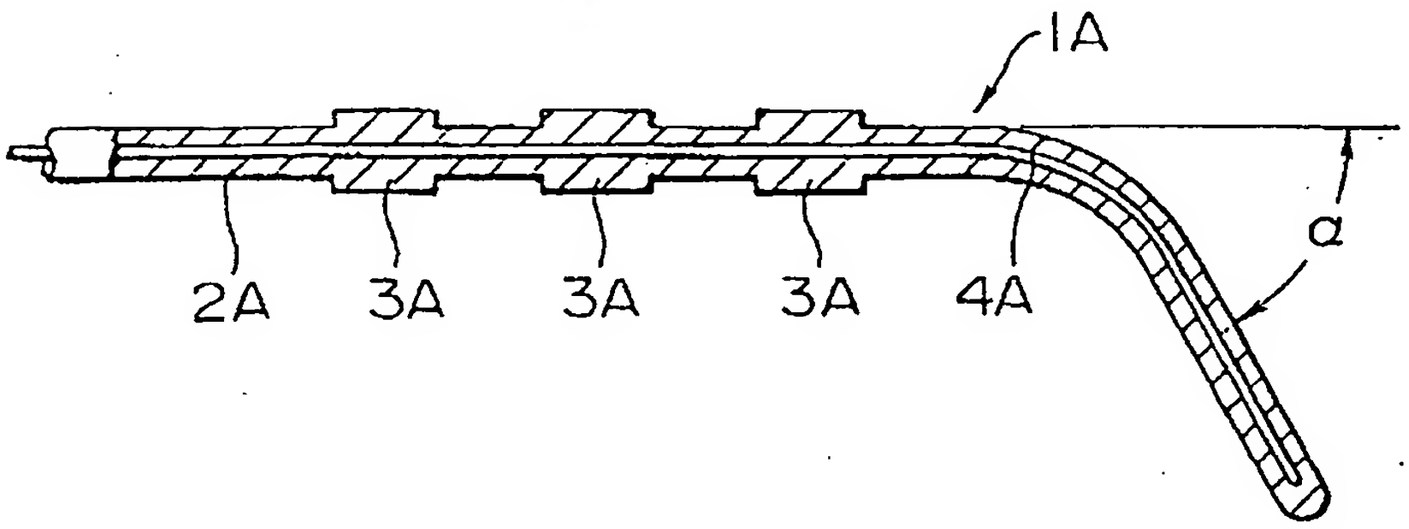


FIG. 3

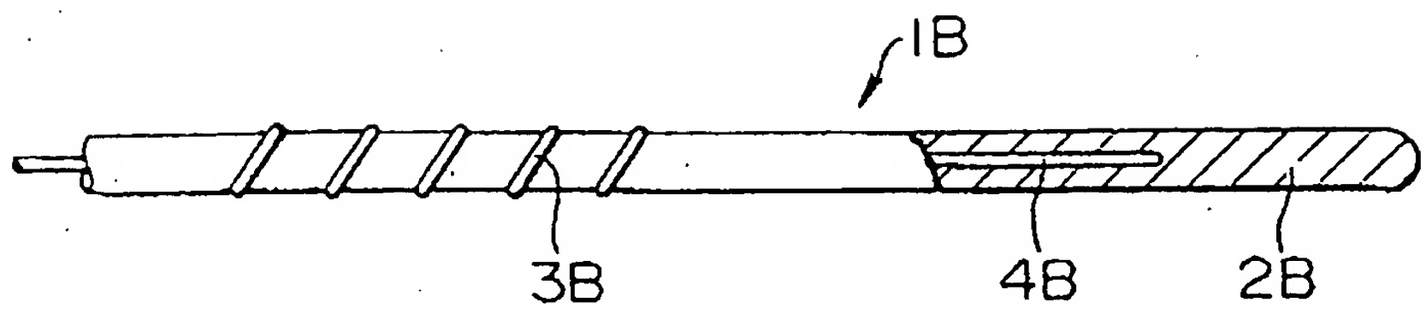


FIG. 4

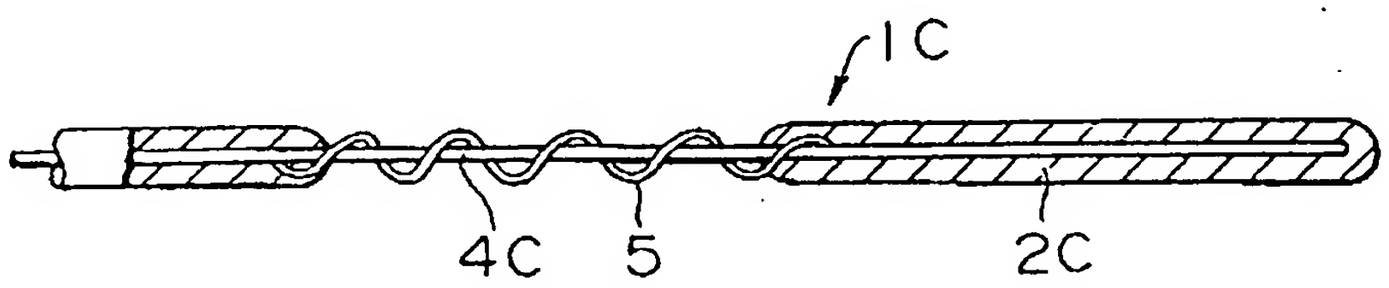


FIG. 5

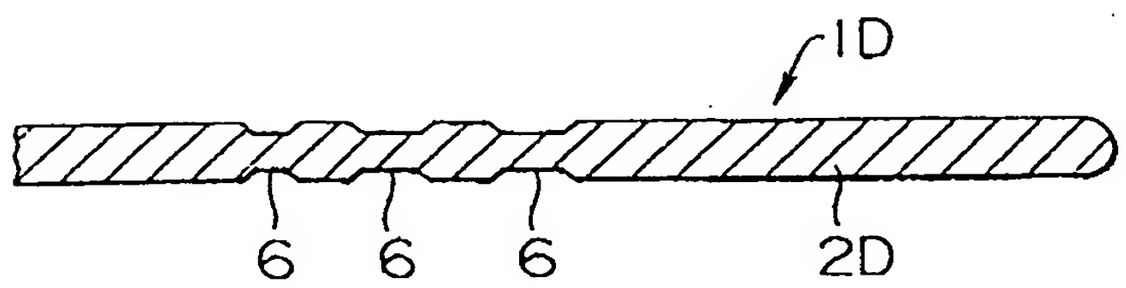


FIG. 6

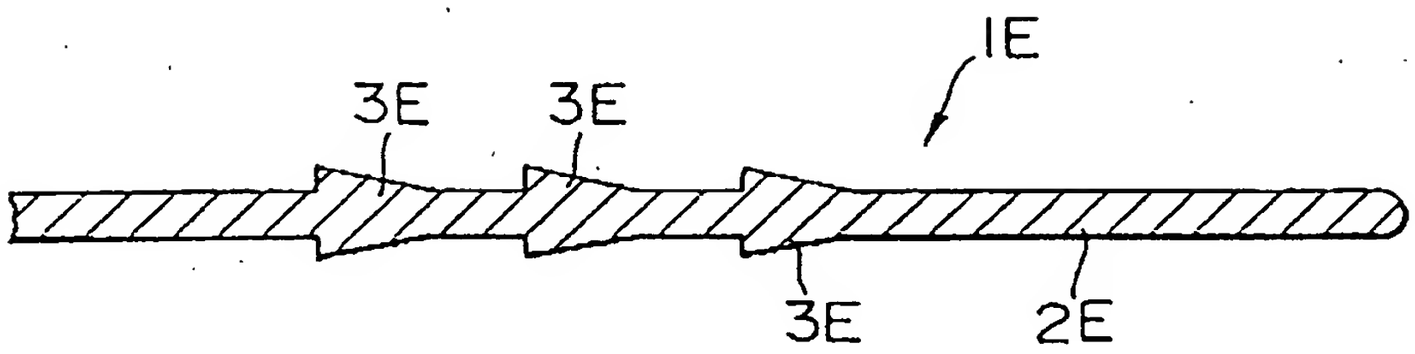


FIG. 7

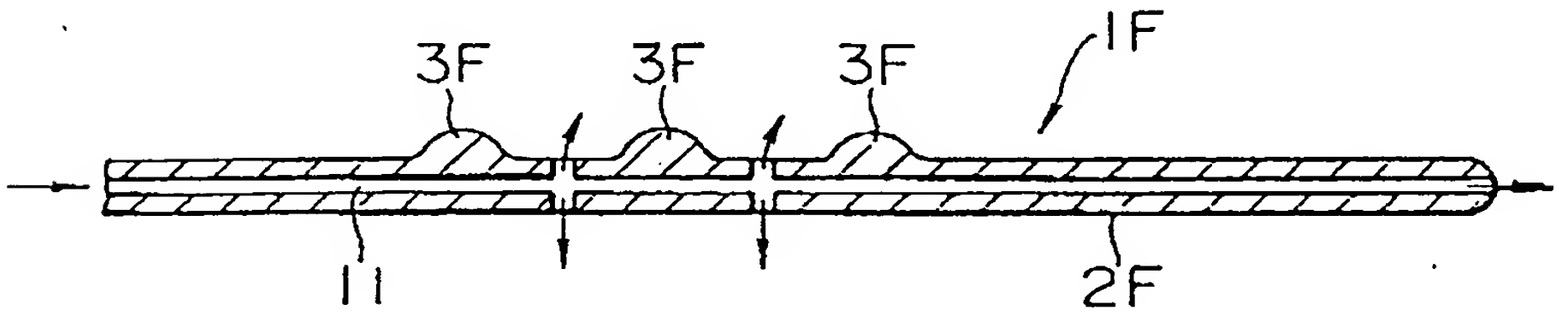


FIG. 8

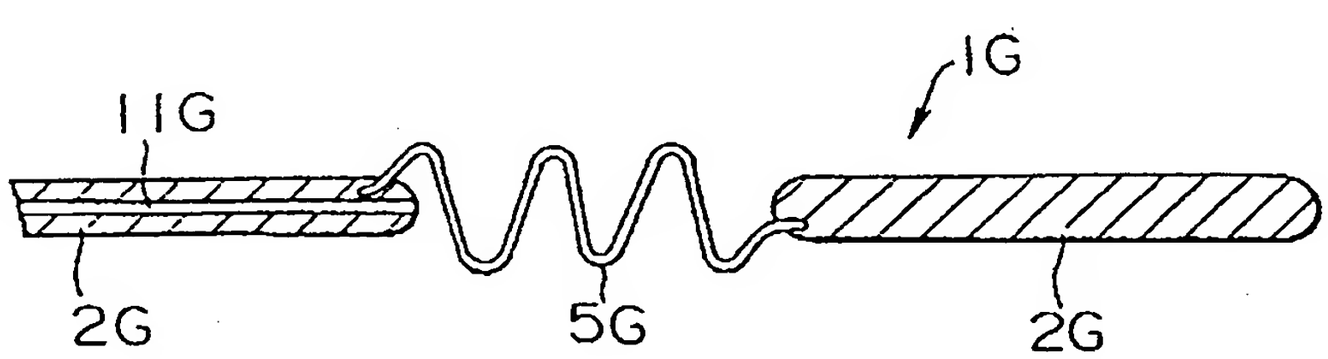


FIG. 9

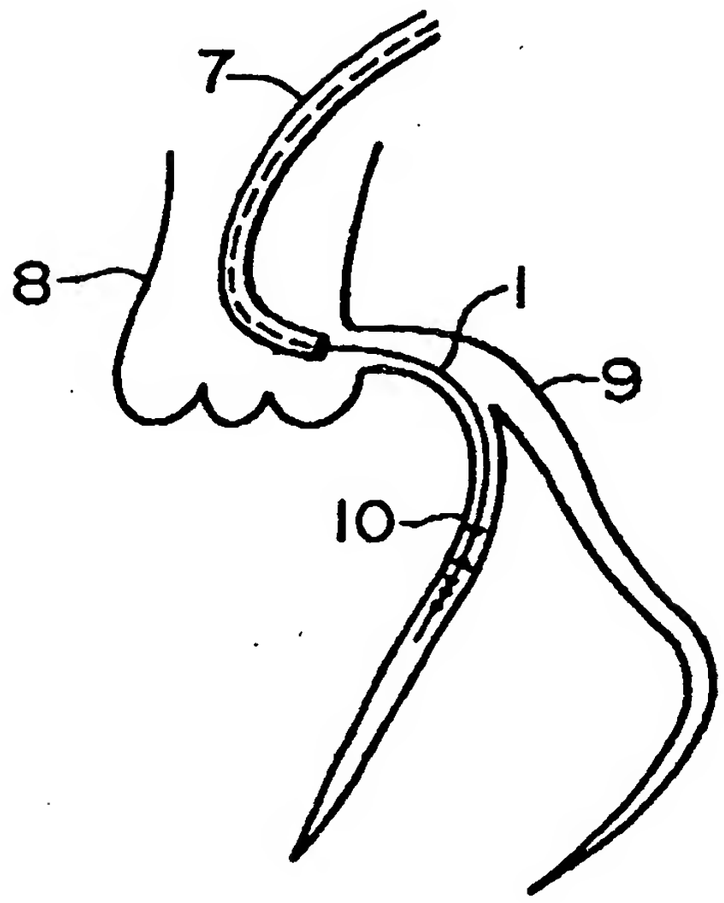
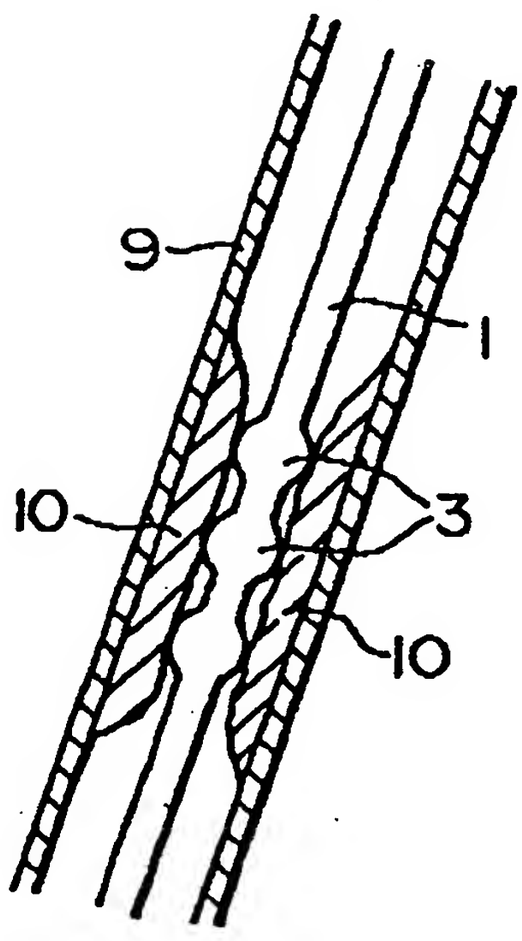


FIG. 10



INTERNATIONAL SEARCH REPORT

International Application No PCT/JP91/00272

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [6]

According to International Patent Classification (IPC) or to both National Classification and IPC

Int. Cl[5] A61B17/00

II. FIELDS SEARCHED

Minimum Documentation Searched [7]

Classification System	Classification Symbols
IPC	A61B17/00

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [8]

Jitsuyo Shinan Koho 1955 - 1990
Kokai Jitsuyo Shinan Koho 1971 - 1990

III. DOCUMENTS CONSIDERED TO BE RELEVANT [9]

Category *	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No. [13]
X	JP, A, 62-231675 (Kato Hatsujo K.K.), October 12, 1987 (12. 10. 87), Pages 1 to 3 (Family: none)	1, 2, 5, 6
X	JP, A, 60-75064 (Cook, Inc.), April 27, 1985 (27. 04. 85), Pages 1 to 5, & US, A, 4548206	3, 5, 6
X	JP, A, 62-231650 (Advanced Technology Laboratories, Inc.), October 12, 1987 (12. 10. 87), Pages 1 to 4 (Family: none)	3, 5, 6
Y	JP, U, 62-157548 (Gunze Ltd.), October 6, 1987 (06. 10. 87), Page 1 (Family: none)	4, 11
Y	JP, A, 62-109560 (Messerschmitt-Bölkow-Blohm GmbH), May 20, 1987 (20. 05. 87), Pages 1 to 6 (Family: none)	9

* Special categories of cited documents: [10]

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
April 30, 1991 (30. 04. 91)	May 20, 1991 (20. 05. 91)
International Searching Authority	**Signature of Authorized Officer**
Japanese Patent Office	

FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

Y	JP, A, 61-113438 (Medical Laser Research and Development Corp.), May 31, 1986 (31. 05. 86), Pages 1 to 14 (Family: none)	9
Y	JP, A, 52-141092 (Nippon Zeon Co., Ltd.), November 25, 1977 (25. 11. 77), Pages 1 to 2 (Family: none)	10, 4

V. ☐ OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE [1]

This international search report has not been established in respect of certain claims under Article 17(2) (a) for the following reasons:

1. ☐ Claim numbers , because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claim numbers , because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claim numbers , because they are dependent claims and are not drafted in accordance with the second and third sentences of PCT Rule 6.4(a).

VI. ☐ OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING [2]

This International Searching Authority found multiple inventions in this international application as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims of the international application.

2. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the international application for which fees were paid, specifically claims:

3. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim numbers:

4. ☐ As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee.

Remark on Protest

☐ The additional search fees were accompanied by applicant's protest.

☐ No protest accompanied the payment of additional search fees.